DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Griffith-Lucas LLC
C/O Mr. Mike Gu
Regulatory Affairs Manager
7th Floor, Jingui Business Building No.982
Congyun Road, Baiyun District
Guangzhou, Guangdong, 510420
CHINA

Re: K140195
Trade/Device Name: Surgical Drape, Model 42526 and 42527
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: Class II
Product Code: KKX
Dated: August 13, 2014
Received: August 18, 2014

Dear Mr. Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by
Richard C. Chapman -S
Date: 2014.09.10
16:53:37 -04'00'

for

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140195

Device Name

Surgical Drape, models 42526 and 42527

Indications for Use *(Describe)*

The Surgical Drape is intended for external use only and is used as a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination. They are provided sterile using ethylene oxide.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	January 06 2014
Submitter:	Manufacturer: GRIFFITH-LUCAS LLC. Address: 6027 STITT ST.MONROE NC, 28110 USA
Primary Contact Person:	Mike Gu Regulatory Affairs Manager OSMUNDA Medical Device Consulting Co., Ltd Tel: (+86) 20-6232 1333 Fax: (+86) 20-8633 0253
Secondary Contact Person:	Bill Marks President GRIFFITH-LUCAS LLC. Ph:(704)283-4667 Fax:(704) 291-7442
Device: Trade Name:	Surgical Drapes
Common/Usual Name:	Surgical Drapes
Regulation description :	Surgical drape and drape accessories
Review panel:	General & Plastic Surgery
Device class:	2
Classification Names:	878.4370
Product Code:	KKX
Predicate Device(s):	DRAPE SURGICAL UTILITY DRAPE STERILE K843496 Busse Surgical Drape I K082297 Dukal 20-001, 20-002 K 083320
Device Description:	Surgical drapes are intended to provide protection from microbial and other contamination. The Lucas surgical drapes described in this submission are one-piece, single use disposable sheets designed to provide an absorbent sterile barrier during surgical procedures. The drapes cover the patient and are made of an absorbent nonwoven fabric backed with a protective film that stops fluid strike-through. There are various sizes to meet the surgeon's needs. In general, the surgeon delineates with proposed field of surgery and charges the nursing team with the responsibility of draping the patient suing different types of drapes, with & without fenestration.
Intended Use:	The Surgical Drape is intended for external use only and is used as covering a protective patient such as to isolate a site of surgical incisions from microbial and other contamination. They are provided

sterile using ethylene oxide.

Technology: Lucas surgical drapes are made of nonwoven fabric composes of a three-layer composite comprised of a top layer, middle layer and bottom layer, they passed the industry standard tests that measure fluid and synthetic blood penetration, they are classified as a level 4 device under the AAMI PB 70 for barrier performance.

Determination of Substantial Equivalence:

Specification	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Proposed Device**
Device name	DRAPE SURGICAL UTILITY DRAPE STERILE	Busse Surgical Drape I	Dukal 20-001, 20-002	SURGICAL DRAPE
K number	K843496	K082297	K 083320	-
Manufacturer	BUSSE HOSPITAL DISPOSABLES, INC	BUSSE HOSPITAL DISPOSABLES, INC	Dukal Corporation	GRIFFITH-LUCAS LLC
Intended Use	The Busse Hospital Disposables is intended for external use only and is used as a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination. They are provided sterile using ethylene oxide.	The Busse Surgical Drape is intended for external use only and is used as a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination. They are provided sterile using ethylene oxide.	The Dukal 20-001- Fenestrated Dukal Surgical Drape, Blue, 18" x 26", with 3" Fenestration, and 20-002 - Dukal Surgical Drape, Blue, 18" x 26" is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.	The Surgical Drape is intended for external use only and is used as a protective patient covering, such as to isolate a site of surgical incisions from microbial and other contamination. They are provided sterile using ethylene oxide.
Materials	Tissue/Poly/Tissue Drape	Tissue/Poly/Tissue Drape	Tissue/Poly/Tissue Drape	Tissue/Poly/Tissue Drape
Sterile	EO	EO	EO	EO
Lamination	Heat welded	Heat welded	Heat welded(three layers)	Heat welded(three layers)
Dimension	Various size	Various size	L*W: 18''*26''; Fenestration: Φ3''	Various size
Barrier properties	AAMI PB70 Barrier Level 4	AAMI PB70 Barrier Level 4	AAMI PB70 Barrier Level 4	AAMI PB70 Barrier Level 4

Environment of Use	During surgeries	During surgeries	During surgeries	During surgeries
Performance	AAMI PB70 Barrier Level 4	AAMI PB70 Barrier Level 4	AAMI PB70 Barrier Level 4	AAMI PB70 Barrier Level 4
Biocompatibility	Non-cytotoxic; Non-sensitizing; Non-irritating; No pyrogen	Non-cytotoxic; Non-sensitizing; Non-irritating; No pyrogen	Non-cytotoxic; Non-sensitizing; Non-irritating; No pyrogen	Non-cytotoxic; Non-sensitizing; Non-irritating; No pyrogen
Other: Device Specific Guidance Requirements for Comparison	Guidance on Premarket Notification 510(k) Submissions for Surgical Gowns and Surgical Drapes	Guidance on Premarket Notification 510(k) Submissions for Surgical Gowns and Surgical Drapes	Guidance on Premarket Notification 510(k) Submissions for Surgical Gowns and Surgical Drapes	Guidance on Premarket Notification 510(k) Submissions for Surgical Gowns and Surgical Drapes

This comparison of the specifications demonstrates the functional equivalence of the products. The differences discussed in this section do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences.

GRIFFITH-LUCAS LLC believes that the SURGICAL DRAPE is as safe and effective, and performs in a substantially equivalent manner to the predicate devices K843496 and K082297.

Summary of Non-Clinical Tests:

The SURGICAL DRAPE had met acceptance criteria for performance testing including biocompatibility (in vitro cytotoxicity, irritation testing, skin sensitization testing and pyrogenicity testing), also the sponsor had performed bench tests to demonstrate that the proposed device performs within its specifications.

1. *AAMI PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities;*
2. *CFR Part 1610 Standard for the Flammability of Clothing Textiles;*
3. *ASTM F 1670-08: Standard test method for resistance of materials used in*

protective clothing to penetration by synthetic blood;

4. *ASTM F1929: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;*
5. *ASTM F1140: Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.*

All tests results met acceptance criteria and were substantially equivalent to the predicate devices.

Summary of Clinical Tests:

The subject of this premarket submission, SURGICAL DRAPE, did not require clinical studies to support substantial equivalence.

Conclusion: GRIFFITH-LUCAS LLC considers the Surgical Drape to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).